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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,667	03/29/2001	Tetsuya Yano	35.C15229	3225

5514 7590 03/11/2003

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/819,667	<b>Applicant(s)</b> YANO ET AL.	
	<b>Examiner</b> Jeanine A Goldberg	<b>Art Unit</b> 1634	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 24 January 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): 112/2<sup>nd</sup> A1-D1.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.

Claim(s) objected to: NONE.

Claim(s) rejected: 1-18.

Claim(s) withdrawn from consideration: 19-25.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because:

With respect to the 112/2nd B, in the final office action, page 3 the rejection has not been overcome by the amendment. Claim 2 recites "a nucleic acid fragment that can be utilized as a primer or probe COMPRISING the nucleic acid according to Claim 1." Claim 1 recites an "isolated nucleic acid CONSISTING OF SEQ ID NO: 1-9 or a modified sequence." Claim 2 is broader in scope than claim 1 because Claim 2 recites COMPRISING whereas Claim 1 recites CONSISTING OF.

With respect to the rejections over 102, the amendment to the Claims fails to overcome the rejections. Engel teaches a primer which is a modified sequences of SEQ ID NO: 1. Brennan teaches every possible 10 mer nucleotides sequence. Therefore, Brennan teaches a modified sequence which is 100% identical over every 10 nucleotides of SEQ ID NO: 1-9. Therefore, the 10 mer nucleotides will hybridize to SEQ ID NO: 1-9. Finally, Huisman teaches the entire PHA gene which comprises SEQ ID NO: 1-9. To the extent that a modified sequence encompasses modifying the primer to include nucleotides on the ends of the sequences, the entire PHA gene would fall within the scope of the claim. SEQ ID NO: 1-9 will hybridize to the full length gene, namely to detect the gene, as one embodiment within the instant application. Thus, the amendments to the claims fail to overcome the 102 rejections.

With respect to the rejections under 103 of Huisman/Solaiman/Dieffenbach, the response asserts that the disclosure fails to render the invention obvious. The response asserts that *In re Deuel* is misapplied. This argument has been thoroughly reviewed, but is not found persuasive because *In re Deuel* is distinguishable from the instant facts. The examiner agrees with the position that the *Deuel* court states "in all of these cases...the prior art teaches a specific, structurally-definable compound and the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention". However, the examiner also notes that *Deuel* teaches at 1215, col. 1, No. 7, "Further, while the general idea of the claimed molecules, their function, and their general chemical nature may have been obvious from Bohlen's teachings, and the knowledge that some gene existed may have been clear, the precise cDNA molecules of claims 5 and 7 would not have been obvious over the Bohlen reference because Bohlen teaches proteins, not the claimed or closely related cDNA molecules". In contrast, in the instant case, the very source of the claimed nucleic acid was provided. The reference even directs the attention to the very region the oligonucleotides are pulled from. *Deuel* did not find it obvious to probe a library to find full length DNA molecules given a smaller portion of the molecule. The instant case, however, is directed to a known full length molecule and determining smaller molecules which may function as probes and/or primers. Thus, the normal circumstances for a *prima facie* case should be followed as set out on 1214, col. 2. Huisman teaches the full length PHA gene comprising SEQ ID NO: 1-9. Specific probes and primers within the nucleic acid are taught by Solaiman. Therefore, the need for structure as asserted by the response has been satisfied given the teachings of the full length gene.

Moreover, the response alludes to *O'Farrell* with respect to the obvious to try standard. The legal standard for "reasonable expectation of success" is provided by caselaw and is summarized in MPEP 2144.08, which notes "obviousness does not require absolute predictability, only a reasonable expectation of success; i.e., a reasonable expectation of obtaining similar properties. See, e.g., *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988)." In this factual case, there is express suggestion in the prior art to select primers which hybridize to the PHA nucleic acid. The prior art teaches the parameters (i.e. size, parameters, homology) necessary to vary to achieve specific probes, and the prior art successfully meets this test. This is sufficient for a reasonable expectation of success.



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